

[Return to CIRM Meetings and Events](#)

State Stem Cell Agency Standards Working Group Agenda 4-29-11

Apr 29, 2011

Main Location:

Premiere Ballroom
HOTEL PALOMAR LOS ANGELES - WESTWOOD
10740 Wilshire Blvd. at Selby Avenue
Los Angeles, CA 90024

Call-in Information:

To join webcast: 1. Go to: <https://cirm.webex.com/cirm/k2/j.php?ED=151267347&UID=1180227247&HMAC=4ecb7af2c0de74d71572982fadd254c1852cf224&RT=MiMo> 2. Enter your name and email address. 3. Enter the session password: april29 4. Click "Join Now". 5. Click "Yes" when asked to participate in Integrated VoIP session. Attendees may join the session up to 15 minutes before the start time. Attendees must have working speakers on their computers to listen to webcast.

Meeting Notice & Agenda

CIRM Live Webcast and 2011 Annual Meeting of the
Scientific and Medical Accountability Standards Working Group
of The California Institute For Regenerative Medicine
Organized Pursuant To The
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

CIRM Live Webcast

Chris Hempel: The Perspective of an iPS Donor Family Participating in Disease Research
Start time: 9:00am
Duration: approximately 40 minutes

Introductions & Updates

1. Welcome from Co-chairs
2. Call to Order & Roll Call
3. Staff Report
4. Report on Scientific Recommendations for iPSC Research Repository
5. Policy Considerations for iPSC Research Repository: Nicole C. Lockhart, Ph.D., Biospecimen Technology Program Specialist in the Office of Biorepositories and Biospecimen Research at the National Cancer Institute of the National Institutes of Health.
6. SWG Policy Deliberations
 - Informed Consent
 - Withdrawal of Subjects from Research
 - Materials Release / Transfer Agreements
 - Return of Data / Clinically Significant Findings
7. Adjourn

Background

In May 2010, the CIRM Standards Working Group convened to examine ethical and policy considerations related to derivation and distribution of induced pluripotent cells (iPSCs). This topic was chosen because CIRM is currently developing a scientific proposal to support the "banking" iPSCs.

- A report based on the May 2010 workshop is available [here](#)

In November 2010, CIRM convened a workshop to assess the scientific need for supporting more formal iPS cell banking efforts. The scientific workshop report identified two independent banking needs: (1) a repository to bank iPS cells generated by the research community in California and (2) a more comprehensive effort to generate iPSCs for disease modeling and in vitro screening of new therapies.

- A report based on the November 2010 workshop is available [here](#)

SWG Ethics / Policy Considerations:

The CIRM SWG is reconvening in April of 2011 in Los Angeles to consider ethics / policy issues in light of this specific banking proposal. Topics for further consideration include:

- Procurement & Sources for Cells and Tissues: What are appropriate consent standards for (1) cells already generated versus new (2) collection efforts to generate iPSCs?
- Withdrawal of Subjects from Research: In addition to established requirements for withdrawal of human subjects from research (45 CFR 46.116(a)(8)) and FDA data retention requirements, should additional policies be considered?
- Transfer of Materials: Transfer agreements should stipulate compliance with established CIRM requirements for research use; should researcher-modified materials be returned to the repository?
- Communication of Results: The generation of iPSCs for disease modeling may result in published findings of interest to donors or individual results on research studies that would alter clinical management of donors. Under what conditions, if any, should information be returned to donors as groups or individuals?

Meeting Goal:

The goal of this meeting is to review these options and recommend operational criteria that will assist CIRM in developing a request for proposal for the iPSC bank.

THE ORDER OF BUSINESS MAY BE CHANGED WITHOUT NOTICE.

NOTICE

The California Institute for Regenerative Medicine and its Independent Citizen's Oversight Committee, and any subcommittees thereof, comply with the Americans with Disabilities Act (ADA) by ensuring that the meeting facilities are accessible to persons with disabilities, and providing that this notice and information given to the Members of the Committee is available to the public in appropriate alternative formats when requested. If you need further assistance, including disability-related modifications or accommodations, you may contact Melissa King at the California Institute for Regenerative Medicine at (415) 396-9100 no later than the day prior to the meeting.

Questions or requests for additional information prior to the Scientific and Medical Research Funding Working Group meeting may be referred to Pat Beaupre Becker at the California Institute for Regenerative Medicine at pbecker@cirm.ca.gov or (415) 396-9105.

Transcripts:



042911_SWG.pdf